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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,219	ROTHSTEIN ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed on April 22, 2004, is acknowledged and has been entered.

2. The amendment filed on November 25, 2003, is acknowledged and has been entered.

3. Claims 1-8 are pending in the application and are currently subject to restriction.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1, 2, 5, 6, and 8, insofar as the claims are drawn to a composition comprising DNA having the polynucleotide sequence of SEQ ID NO: 2, an isolated RNA transcribed from said DNA, an expression construct comprising said DNA, cells comprising said expression construct, and primers consisting of 12 to 18 base pairs of SEQ ID NO: 2, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, and class 536, subclass 24.33.

Group II. Claims 1, 2, 5, 6, and 8, insofar as the claims are drawn to a composition comprising DNA having the polynucleotide sequence of SEQ ID NO: 3, an isolated RNA transcribed from said DNA, an expression construct comprising said DNA, cells comprising said expression construct, and primers consisting of 12 to 18 base pairs of SEQ ID NO: 3, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, and class 536, subclass 24.33.

Group III. Claims 1, 2, 5, 6, and 8, insofar as the claims are drawn to a composition comprising DNA having the polynucleotide sequence of SEQ ID NO: 4, an isolated RNA transcribed from said DNA, an expression

construct comprising said DNA, cells comprising said expression construct, and primers consisting of 12 to 18 base pairs of SEQ ID NO: 4, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, and class 536, subclass 24.33.

Group IV. Claims 1, 2, 5, 6, and 8, insofar as the claims are drawn to a composition comprising DNA having the polynucleotide sequence of SEQ ID NO: 5, an isolated RNA transcribed from said DNA, an expression construct comprising said DNA, cells comprising said expression construct, and primers consisting of 12 to 18 base pairs of SEQ ID NO: 5, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, and class 536, subclass 24.33.

Group V. Claims 1, 2, 5, 6, and 8, insofar as the claims are drawn to a composition comprising DNA having the polynucleotide sequence of SEQ ID NO: 6 or portion thereof, an isolated RNA transcribed from said DNA or portion thereof, an expression construct comprising said DNA or portion thereof, cells comprising said expression construct, and primers consisting of 12 to 18 base pairs of SEQ ID NO: 6, classified, for example, in class 536, subclass 23.5, class 435, subclass 320.1, and class 435, subclass 325, and class 536, subclass 24.33.

Group VI. Claim 3, insofar as the claim is drawn to an isolated protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 2, classified, for example, in class 530, subclass 350.

Group VII. Claim 3, insofar as the claim is drawn to an isolated protein translated from an isolated RNA transcribed from DNA having the

polynucleotide sequence of SEQ ID NO: 3, classified, for example, in class 530, subclass 350.

Group VIII. Claim 3, insofar as the claim is drawn to an isolated protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 4, classified, for example, in class 530, subclass 350.

Group IX. Claim 3, insofar as the claim is drawn to an isolated protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 5, classified, for example, in class 530, subclass 350.

Group X. Claim 3, insofar as the claim is drawn to an isolated protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 6 or portion thereof, classified, for example, in class 530, subclass 350.

Group XI. Claim 4, insofar as the claim is drawn to an isolated antibodies produced from a protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 2, classified, for example, in class 530, subclass 387.9.

Group XII. Claim 4, insofar as the claim is drawn to an isolated antibodies produced from a protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 3, classified, for example, in class 530, subclass 387.9.

Group XIII. Claim 4, insofar as the claim is drawn to an isolated antibodies produced from a protein translated from an isolated RNA transcribed from

DNA having the polynucleotide sequence of SEQ ID NO: 4, classified, for example, in class 530, subclass 387.9.

Group XIV. Claim 4, insofar as the claim is drawn to an isolated antibodies produced from a protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 5, classified, for example, in class 530, subclass 387.9.

Group XV. Claim 4, insofar as the claim is drawn to an isolated antibodies produced from a protein translated from an isolated RNA transcribed from DNA having the polynucleotide sequence of SEQ ID NO: 6 or portion thereof, classified, for example, in class 530, subclass 387.9.

Group XVI. Claim 7, insofar as the claim is drawn to a method for screening a compound, said method comprising providing cells containing an expression vector comprising at least a portion of the sequences of SEQ ID NO: 2 or variants or homologs thereof and contacting said cells with a compound, classified in class 435, subclass 375.

Group XVII. Claim 7, insofar as the claim is drawn to a method for screening a compound, said method comprising providing cells containing an expression vector comprising at least a portion of the sequences of SEQ ID NO: 3 or variants or homologs thereof and contacting said cells with a compound, classified in class 435, subclass 375.

Group XVIII. Claim 7, insofar as the claim is drawn to a method for screening a compound, said method comprising providing cells containing an expression vector comprising at least a portion of the sequences of SEQ ID NO: 4 or variants or homologs thereof and contacting said cells with a compound, classified in class 435, subclass 375.

Group XIX. Claim 7, insofar as the claim is drawn to a method for screening a compound, said method comprising providing cells containing an expression vector comprising at least a portion of the sequences of SEQ ID NO: 5 or variants or homologs thereof and contacting said cells with a compound, classified in class 435, subclass 375.

Group XX. Claim 7, insofar as the claim is drawn to a method for screening a compound, said method comprising providing cells containing an expression vector comprising at least a portion of the sequences of SEQ ID NO: 6 or variants or homologs thereof and contacting said cells with a compound, classified in class 435, subclass 375.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XV are products, whereas the inventions of Groups XVI-XX are processes.

The inventions of Group I and the inventions of Groups XVII-XX are unrelated because the products of Group I are not specifically used or otherwise involved in the processes of Groups XVII-XX.

The inventions of Group II and the inventions of Groups XVI and XVIII-XX are unrelated because the products of Group II are not specifically used or otherwise involved in the processes of Groups XVI and XVIII-XX.

The inventions of Group III and the inventions of Groups XVI, XVII, XIX, and XX are unrelated because the products of Group III are not specifically used or otherwise involved in the processes of Groups XVI, XVII, XIX, and XX.

The inventions of Group IV and the inventions of Groups XVI-XVIII and XX are unrelated because the products of Group IV are not specifically used or otherwise involved in the processes of Groups XVI-XVIII and XX.

The inventions of Group V and the inventions of Groups XVI-XIX are unrelated because the products of Group V are not specifically used or otherwise involved in the processes of Groups XVI-XIX.

The inventions of Groups I-V and the inventions of Groups XVI-XX, respectively, are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed, namely the cell containing a recombinant vector comprising a DNA having a particular polynucleotide sequence can be used in a materially different process of using that product, such as the process of using those cells to produce a protein encoded by the polynucleotide sequence of the vector.

The inventions of Groups I-V and the inventions of Groups XVI-XX, respectively, have acquired a separate status in the art, as evidenced by their different classifications and/or art-recognized divergence in subject matter, and the search performed in examining claims drawn to a product is a different from the search performed in examining claims drawn to a process using that product. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims of Group Groups I-V would not suffice to provide adequate information regarding the merit of the claims of Group XVI-XX, respectively, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of Groups I-V and the inventions of Groups XVI-XX, respectively, an examination of both would constitute a serious burden.

Since the inventions of Groups I-V and the inventions of Groups XVI-XX, respectively, have been shown to be patentably distinct, and because the examination of both inventions could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

The inventions of Groups I-XV are patentably distinct for the following reasons:

The inventions of Groups I-V are nucleic acid molecules, vectors comprising such nucleic acid molecules, host cells comprising such nucleic acid molecules, or primers consisting of a portion of the sequence of said nucleic acid molecules; the inventions of Groups VI-X are polypeptides; and the inventions of Groups XI-XV are antibodies.

Polypeptides and polynucleotides are chemically distinct products, since polypeptides are composed of polymers of amino acids, whereas polynucleotides are composed of polymers of nucleotides. Any relationship between a polynucleotide and a polypeptide is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, a polypeptide can be produced by means, other than the recombinant means by which a polynucleotide encoding a polypeptide might be used to produce the polypeptide, since a polypeptide can be produced (or isolated) by biochemical means, including, for example, affinity chromatography. In addition, while the polynucleotide might encode the polypeptide, generally, it can also encode another polypeptide using the information provided by an alternative open reading frame; and furthermore, since a polynucleotide can be used as a probe in hybridization-based analyses, the information provided by a polynucleotide can be used isolate different polynucleotides encoding polypeptides, which have amino acid sequences that differ from the amino acid sequence encoded by the disclosed polynucleotide. Consequently, the disclosed relationship between a polynucleotide capable of encoding a polypeptide and the polypeptide is not exclusive, since either the

claimed polynucleotide or the claimed polypeptide can also be related to other polynucleotides or polypeptides, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups VI-X and the inventions of Groups I-V, respectively, are patentably distinct products.

The inventions of Groups VI-X and the inventions of Groups I-V, respectively, have acquired a separate status in the art, as evidenced by their different classifications, and the search performed in examining claims drawn to a polynucleotide is a different from the search performed in examining claims drawn to a polypeptide. Apart from the searching patent databases using the patent classification of the claimed subject matter, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, the search and considerations necessary in examining the merit of claims directed to the inventions of any of Groups I-V would not suffice to provide adequate information regarding the merit of the claims directed to the inventions of any of Groups VI-X, respectively, and vice versa, since the searches are not the same, nor are they one coextensive in scope and nature. Because different searches would have to be performed to examine the inventions of any of Groups I-V and the inventions of any of Groups VI-X, respectively, an examination of both would constitute a serious burden. Moreover, because the disclosed relationship between the polynucleotide and the polypeptide encoded by the polynucleotide is not absolute or exclusive of other relationships with different polynucleotides or polypeptides, the search of either group will likely provide information that is relevant to one but not the other; and as such, searching one in addition to the other would be unduly burdensome.

Since the inventions of Groups I-V and the inventions of any of Groups VI-X, respectively, are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

An antibody, such as an immunoglobulin G (IgG) molecule, typically comprises four polypeptides: two light chains and two heavy chains, each containing constant and variable regions, which interact with one another to form an antigen-binding domain comprised of amino acid residues in each chain. In contrast, claims polypeptides are disclosed as consisting of a single polypeptide chain; so the inventions of Groups VI-X and the inventions of Groups XI-XV, respectively, are structurally distinct from one another. Thus, any relationship between an antibody and a polypeptide to which the antibody binds is codependent upon the structural (i.e., antigenic) information provided by the polypeptide, which is recognized as the antigenic determinant to which the antibody binds, and the selective binding nature of the antigen-binding domain of the antibody. However, a polypeptide comprises multiple antigenic determinants and can thus elicit the production of multiple different antibodies, which recognize and bind structurally distinct portions (i.e., epitopes) of the polypeptide. Furthermore, an antibody is capable of recognizing and binding antigenic determinants that are shared by polypeptides, which are otherwise structurally and/or functionally distinct from the claimed polypeptide to which it binds (e.g., a human protein's mouse homolog, or a different member of a functionally related family of proteins). Consequently, the disclosed relationship between an antibody that binds a polypeptide and the polypeptide is not exclusive, since either the claimed antibody or the claimed polypeptide can also be related to other polypeptides or antibodies, respectively, which are materially and chemically different from the claimed inventions. Therefore, the inventions of Groups VI-X and the inventions of Groups XI-XV, respectively, are patentably distinct products.

Searching both the inventions of Groups VI-X and the inventions of Groups XI-XV, respectively, would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. A search of relevant sequence databases using the entire amino acid sequence of the polypeptide as query is necessary for the determination of the novelty and unobviousness of the polypeptide. However, such a search is not necessary, or sufficient to identify antibodies that bind the polypeptide, since antibodies

that bind an epitope of the polypeptide may be known, even if the polypeptide is not (e.g., a anti-phosphotyrosine antibody binds a phosphotyrosine epitope, which is shared by numerous different proteins, and which would bind a novel tyrosine phosphorylated polypeptide). Accordingly, a thorough search of the technical literature is particularly pertinent, and since such a search is performed by a series of key word queries of relevant databases, each search would be performed using a different set or series of key words. Therefore, having to search both the inventions of Groups VI-X and the inventions of Groups XI-XV, respectively, would constitute a serious burden.

Since the inventions of Groups VI-X and the inventions of Groups XI-XV, respectively, are patentably distinct and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups I-V are nucleic acid molecules, vectors comprising such nucleic acid molecules, host cells comprising such nucleic acid molecules, or primers; in contrast, the inventions of Groups XI-XV are antibodies. A polynucleotide is composed of polymers of nucleotides, whereas antibodies are composed of polymers of amino acids. Any relationship between a polynucleotide and a polypeptide (e.g., an antibody) is dependent upon the information provided by the nucleotide sequence of the polynucleotide, as it corresponds to an "open reading frame" encoding the amino acid sequence of the polypeptide. However, the claimed polynucleotide does not encode a polypeptide chain of the claimed antibody; and the claimed antibody cannot be encoded by the claimed polynucleotide. Therefore, the inventions of Groups I-V and the inventions of Groups XI-XV, respectively, are patentably distinct products.

Searching both the inventions Groups I-V and the inventions of Groups XI-XV, respectively, would be unduly burdensome, because the inventions have acquired a separate status in the arts, as evidenced by their separate classifications, and moreover because the necessary searches are not the same, nor are they coextensive in nature and scope with one another. Therefore, having to search both the inventions of Groups I-V and the inventions of Groups XI-XV, respectively, would constitute a serious burden.

Since the inventions of Groups I-V and the inventions of Groups XI-XV, respectively, are patentably distinct from the other and because the examination of both could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups I-V are patentably distinct, each from the others, because each is, or comprises a nucleic acid molecule, a vector comprising such a nucleic acid molecule, a host cell comprising such a nucleic acid molecule, wherein the nucleic acid molecule comprises a distinct polynucleotide sequence that is disclosed as encoding a different protein comprising a distinct amino acid sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups I-V is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups I-V are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups VI-X are patentably distinct, each from the others, because each is a protein comprising a distinct amino acid sequence, which is encoded by a nucleic acid molecule having a distinct polynucleotide sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups VI-X is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups VI-X are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

The inventions of Groups XI-XV are patentably distinct, each from the others, because each is an antibody that binds a protein comprising a distinct amino acid sequence, which is encoded by a nucleic acid molecule having a distinct polynucleotide sequence.

Because of the these differences, the search necessary to examine claims directed to any of the inventions of Groups XI-XV is not the same, nor is it coextensive with the search necessary to examine claims directed to any of the others. Accordingly, a separate and different search would have to be performed to examine claims directed to any one of these groups of inventions. Therefore, the examination of more than one of the inventions would constitute a serious burden.

Since the inventions of Groups XI-XV are patentably distinct from the others and because the examination of more than one could not be made without serious burden, it is proper to restrict one from the other. See MPEP § 803.

6. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
May 30, 2006